

REMARKS

Claims 1, 4-19, 24 and 25 have been amended herein. Claims 1, 14, 24 and 25 have been amended to eliminate typographical errors. Claims 4-19 have been amended from multiple dependent claims to singly dependent claims.

Species Election

Applicant acknowledges that the election of species requirement over claim 24 has been withdrawn.

Claim Objection

Claim 23 was objected to as being in improper form because it is a multiple dependent claim, which depends on other multidependent claims. Claims 4-19 have been amended to depend solely from claim 1. Therefore, claim 23 no longer depends on other multidependent claims. Thus, claim 23 is now in a proper form, and this objection should be withdrawn.

Claim Rejections

35 U.S.C. 112, second paragraph

Claims 1-8, 10-15, 17-22 and 24-28 were rejected as being indefinite for various reasons. Applicant has amended claims 1, 8, 13, 14 and 25 herein. In claim 1, the phrase "of a nondrug" is changed to "or a nondrug". The terms "anyone" and "anyon" are cancelled in claims 8 and 13, respectively. In claim 14, the term "is" is replaced with the term "or". In claim 25, the term "nonsuitable" is changed to "unsuitable". Applicant contends that the amendments to claims 1, 8, 13, 14 and 25 render claims 1-8, 10-15, 17-22 and 24-28 clear and definite in satisfaction of 35 U.S.C. 112, second paragraph. Therefore, Applicant requests reconsideration and withdrawal of this rejection.

35 U.S.C. 103(a)

Claims 1-8, 15, 18-22, and 24-28 were rejected under 35 U.S.C. 103(a) as being unpatentable over Fuisz (U.S. Pat. No. 5,429,836). According to the Examiner, Fuisz teaches flakes. The Examiner also states that maltodextrin, actives, food carriers,

cosmetics, ice cream, gels, enhanced food products and medical delivery are disclosed by Fuisz. Therefore, the Examiner asserts that, in view of Fuisz, it would have been obvious to make flakes for the beneficial effect of enhanced food products and medical delivery. In addition, the Examiner contends that the claimed dimensions are within the skill of the art to achieve a beneficial effect and are not considered critical absent evidence to the contrary. *See* Office Action at page 3. Applicant traverses.

"In determining whether the invention as a whole would have been obvious under 35 U.S.C. 103, we must first delineate the invention as a whole. In delineating the invention as a whole, we look not only to the subject matter which is literally recited in the claim in question . . . but also to those properties of the subject matter which are inherent in the subject matter *and* are disclosed in the specification. . . Just as we look to a chemical and its properties when we examine the obviousness of a composition of matter claim, it is this invention *as a whole*, and not some part of it which must be obvious under 35 U.S.C. 103." MPEP § 2141.02 quoting *In re Antonie*, 559 F.2d 618, 620, 195 USPQ 6, 8 (CCPA 1977) (emphasis in original) (citations omitted).

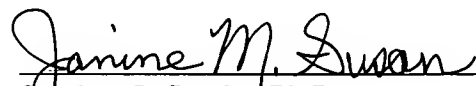
Independent claims 1 and 20 are both directed to substantially flat flakes wherein the length and the width of the flakes are each at least three times the thickness, and wherein the longest dimension of each flake is between 100 nanometers and 5 millimeters. The dimensions establish the ratio between the thickness and the surface area of the claimed flakes. The established ratio is critical in order to generate a straight line dissolution and drug uptake curve rather than a bolus dose distribution curve of release. In other words, the flakes dissolve over time in order to achieve a specified drug release profile rather than dissolving instantaneously. *See* Specification at page 8, lines 23-29. Therefore, the claimed invention as a whole is the flakes with specific dimensions that establish a critical ratio between the thickness and the surface area, which impart the inherent properties of a straight line dissolution and drug uptake curve.

In contrast, the compositions described by Fuisz are specifically derived from a feedstock, which is primarily maltooligosaccharides. The feedstock is subjected to flash heating in order to change the chemical structure of the feedstock. The objective is to create a matrix for use as an ingredient for bulking and dispersing in food products. *See* Fuisz at column 4, lines 32-35. In contrast to the flakes described and claimed in the

present application, the flakes mentioned in Fuisz are designed to instantaneously dissolve in liquids. *See* Fuisz at column 4, lines 43-53 and lines 59-63. Moreover, there is no mention of the dimensions of the flakes that result from the flash flow process used in Fuisz. Most importantly, there is no teaching or suggestion in Fuisz to modify the flakes of maltodextrin matrix in order to alter the dissolution properties. Therefore, the flakes as claimed in the present invention are not obvious in view of Fuisz. Thus, Applicant requests reconsideration and withdrawal of this rejection.

Applicant submits that the claims, as amended herein, are in condition for allowance. The Examiner is encouraged to call the undersigned attorney at (617) 854-4069 should he determine that a telephonic interview would expedite prosecution of this case.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Stephen J. Gaudet", is written over a horizontal line.

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Date: August 8, 2005